

### **Remarks**

Applicants appreciate the thorough examination of the present application as evidenced by the final Office Action dated November 17, 2005 ("the Final Action"). Applicants further appreciate the Examiner's indication that Claims 49, 52 and 53 are allowed. Applicants also express their gratitude to the Examiner in view of Examiner's willingness to conduct a telephonic interview with the Applicants' representative as discussed in further detail below.

Claims 40, 43, 45-49, 52, 53 and 56-69 stand rejected. Upon entry of the present Amendment, Claims 40, 43, 45-47, 49, 52, 53, 56-65, 69 and 70 are pending in the present application. Applicants address the concerns raised in the Final Action in the comments provided below.

#### **I. Interview Summary**

Applicants extend their gratitude to Examiner Phuong N. Huynh, Ph.D. for the telephonic interview conducted on April 18, 2006 with Applicants' representative, Shawna Cannon Lemon.

The participants discussed the proposed claim amendments previously forwarded to the Examiner by Applicants' representative. The Examiner provided additional suggestions for claim amendments, which have been included in the claim amendments presented herein. The Examiner indicated that the claim amendments, as discussed, may address the issues pertaining to the rejection under 35 U.S.C. § 112, second paragraph. The Examiner further indicated that the Applicants should specifically cite support in the application for the claim amendments.

In view of the helpful and constructive dialog expressed during this interview, Applicants set forth the claim amendments and additional remarks presented herein in support of the patentability of the pending claims.

#### **III. Claim Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 40, 42, 43, 45-48 and 56-69 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. *See* Final Action, page 2. Pursuant to the discussion with the Examiner as noted above, Applicants have amended the claims to address these rejections.

More specifically, Applicants have amended Claim 40 so that Claim 40 is directed to a method for diagnosing hemostatic dysfunction comprising an inflammatory condition, as suggested by the Examiner. Applicants have also amended Claim 40 to include the recitation "wherein a greater formation of complex correlates to the presence of hemostatic dysfunction comprising an inflammatory condition." Claim 40 further includes the recitations directed to the specific Markush groups as suggested by the Examiner.

Claim 45 has been amended and is now directed to a method for monitoring hemostatic dysfunction comprising an inflammatory condition. Amended Claim 45 includes the following recitation:

forming an initial complex and an additional complex that are measured over time to provide respective first and second time-dependent measurement profiles, wherein (a) an increase in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a progression of the hemostatic dysfunction comprising the inflammatory condition, and (b) a decrease in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a regression of the hemostatic dysfunction comprising the inflammatory condition.

Applicants have amended Claim 61 to clarify step d) such that this step now recites "comparing a slope and/or total change in the respective first and second time-dependent measurement profiles to diagnose the hemostatic dysfunction comprising the inflammatory condition."

Applicants have added new Claim 70 directed to a method for monitoring hemostatic dysfunction comprising an inflammatory condition as suggested by the Examiner in view of amending Claim 40 to recite a method for diagnosing hemostatic dysfunction comprising an inflammatory condition.

Support for these claim amendments can be found in the specification as originally filed, for example, page 3, lines 10-29; page 4, lines 1-12; page 29, lines 23-34; page 34, lines 16-20; page 35, line 11 through page 36, line 2; page 39, lines 4-8 and line 33 through page 40, line 8. Support can also be found in the originally filed claims and figures of the present application.

Accordingly, Applicants submit that, for at least the foregoing reasons, the rejection of Claims 40, 42, 43, 45-48 and 56-69 have been overcome, and new Claim 70 is patentable.

**Conclusion**

Applicants respectfully submit that, for at least the reasons discussed above, the amendments and remarks address the outstanding rejections of the claims. Accordingly, Applicants respectfully request allowance of all the pending claims and passing this application to issue.

In the event that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

The Examiner is encouraged to direct any questions regarding the foregoing to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,




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Susan E. Freedman

Date of Signature: April 28, 2006